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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-------------------------|------------------------|------------------|
| 10/581,575 | 06/02/2006 | Mi Rim Jin | DI-010 | 3611 |
| 38051 | 7590 | 09/20/2007 | EXAMINER MI, QIUWEN | |
| KIRK HAHN 14431 HOLT AVE SANTA ANA, CA 92705 | | | ART UNIT 1655 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|-----------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/581,575 | JIN ET AL. |
| | Examiner Qiuwen Mi | Art Unit 1655 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 August 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-14 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 02 June 2006 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Applicant's amendment in the reply filed on 8/20/07 is acknowledged. Any rejection that is not reiterated is hereby withdrawn.

Claims Pending

Claim 14 is newly submitted. Claims 1-14 are pending. Claims 1-14 are examined on the merits.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/581,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed compound with formula (1a) is inherently in the chloroform fraction of the polar solvent extract of Cucurbitaceae family, thus claims 1-6 of copending Application No. 10/581,576 'anticipate' the Claims 1-14 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections –35 USC § 112, 1st

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Obesity and adipogenesis-involved diseases cannot be prevented. There is no evidence that one would not ever get obesity and adipogenesis-involved diseases by consuming the claimed plant extract. Unless Applicant can show on the record that obesity and adipogenesis-involved diseases would be completely prevented in every instance, Applicant is requested to cancel the word “prevention”.

Claims 1, 2, and 5-12 are drawn to a purified extract isolated from Cucurbitaceae family plant.

The MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claims 1, 2, and 5-12 are broad generics, with respect to all possible plants from the family Cucurbitaceae. [Wikipedia Online](#) indicates that the Cucurbitaceae family has 118 extant genera in Cucurbitaceae, including 825 species. The specification lacks sufficient variety of species reflect the large variance within the family Rosaceae, Vitaceae, Umbelliferae or the whole plant kingdom.

It is well known in the art that multitudes of proteins and natural compounds have been isolated from a crude aqueous extract of a plant, and each crude aqueous extract obtained from a plant is unpredictable in nature. It is the opinion of the Examiner that the specification does not provide adequate written description of any species of Cucurbitaceae family, and what Applicant is in possession is a purified extract isolated from pumpkin, water-melon, sponge gourd, gourd, and cucumber as indicated in claims 3 and 4.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed. The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed.” (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed compound being claimed, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the compound. Adequate written description requires more than a mere statement of the total amount of the plant material being used. See

Fiers v. Revel, 25USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18USPQ2d 1016.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F. 2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does “little more than outline [goals] appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.”) Accordingly, it is deemed that the specification fails to provide adequate written description for the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention.

Claim Rejections –35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “subjecting said chloroform-soluble fraction to silica gel column chromatography with a solvent mixture of hexane: chloroform: methanol (16:15:1) to obtain 11 sub-fractions, subjecting 9th fraction...”, without knowing the flow rate and amount of solvent

being used, the claim fails to point out how to collect the 11 sub-fractions, and thus the 9th sub-fractions is indefinite.

Although claims 2-14 are not specifically recited for containing indefinite matter, because these claims are dependant upon claim 1, claims 2-14 necessarily comprise all of the limitations of claim 1. Because claims 2-14 do not remedy the indefiniteness of claim 1, these claims are also properly rejected under this statute.

Claim Rejections –35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility or a well established utility. The claims recite “prevention ...of obesity and adipogenesis-involved diseases”. The broadest reasonable interpretation of the term obesity and adipogenesis-involved diseases merely require that one subject gets obese. There is no evidence that obesity and adipogenesis-involved diseases would be prevented, therefore the utility would not be credible.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 59203451, in view Tang et al (Zhongcaoyao 32(9), 773-775, 2001).

JP 59203451 teaches saponins (inherently water soluble) isolated from aerial parts of *Luffa cylindrical* (Curcurbitaceae family) are health food additives that are effective in controlling obesity (see Abstract, translation has been ordered).

JP 59203451 does not teach the detailed isolation procedure as claimed.

Tang et al teach that a crude extract of root of *Luffa cylindrical* was prepared by decocting with boiling water, chromatographed on microporous resin column, and eluted by 60% ethanol. The eluant was separated on silica gel column by eluting with chloroform, and various proportions of chloroform-acetone, and chloroform-methanol. Eleven compounds were isolated and identified as triterpenoid saponins (see Abstract, translation has been ordered).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to isolate the purified extract from plant *Luffa cylindrical* for anti-obesity

purpose since JP 59203451 teaches that the saponins isolated from aerial parts of *Luffa cylindrical* are health food additives that are effective in controlling obesity.

Even though JP 59203451 does not teach the water extract being fractionated with hexane, chloroform, ethylacetate, butanol solvent with increasing order, and then subjected the chloroform extract to silica gel chromatography to obtain chloroform-soluble 11-sub-fraction as claimed, since claims 1-14 are product by process claims, and the nature of the purified extract is undisclosed (for instance, the structure or the name of the compound), it is deemed that the saponin in JP 59203451 meets the request of a purified extract isolated from Curcurbitaceae family as it is water soluble, and it is effective in controlling obesity as claimed, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

It is further clear from Tang et al that 11 saponins from *Luffa cylindrical* will be soluble in water, and will be further soluble in solvent chloroform or a chloroform-methanol mixture, as instantly claimed.

Since the invention of JP 59203451 yielded beneficial results in obesity control, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation of the detailed isolation procedure, such as the extraction time, fractionation with hexane, chloroform, ethylacetate, butanol solvent with increasing order, chloroform-soluble 11-sub-fraction, or using the proper eluent, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Choosing from a finite number of predictable solutions would have been obvious because a person of ordinary skill has good reason to pursue

the known options with his or her technical grasps. If this leads to the anticipated success, it is likely the product not of innovation, but of ordinary skill and common sense.

With respect to the art rejection above, please note that Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' method differs and, if so, to what extent, from that of discussed references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Answer to Applicant's Argument

Applicant's arguments with respect to the rejection(s) of claim(s) under references Yoshikawa et al and Evertz have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Tang et al (Zhongcaoyao 32(9), 773-775, 2001), and JP 59203451.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Qiuwen Mi

/Patricia Leith/

Patricia Leith

Primary Examiner

AU 1655